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# **FEDERAL RULEMAKING**

## **Procedural and Analytical Requirements at OSHA and Other Agencies**

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Strategic Issues



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<b>Abstract</b> I am pleased to be here today to discuss the procedural and analytical rulemaking requirements applicable to the Occupational Safety and Health Administration (OSHA) and, in many cases, other federal regulatory agencies. The requirements are contained in a number of statutes and executive orders governing the rulemaking process, and the scope of the requirements varies dramatically. Various actors are involved in this process, including Congress, the president, the Office of Management and Budget (OMB), and, most recently, GAO.		
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I am pleased to be here today to discuss the procedural and analytical rulemaking requirements applicable to the Occupational Safety and Health Administration (OSHA) and, in many cases, other federal regulatory agencies. The requirements are contained in a number of statutes and executive orders governing the rulemaking process, and the scope of the requirements varies dramatically. Various actors are involved in this process, including Congress, the president, the Office of Management and Budget (OMB), and, most recently, GAO.

First, I would like to identify and describe the major statutory rulemaking requirements that apply to many, and in some cases all, federal agencies. These requirements are contained in such statutes as the Administrative Procedure Act, the Paperwork Reduction Act, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act. Then I would like to identify and describe some of the executive branch requirements that apply to the rulemaking process, most notably Executive Order 12866 on regulatory planning and review. As I mentioned previously, we have examined the implementation of many of these statutory and executive branch rulemaking requirements, and I will discuss the results of our reviews in the process of listing the requirements. Finally, I will note a relatively recent statute that involves the legislative branch in the rulemaking process.

In brief, the rulemaking requirements that have been placed on OSHA and other agencies over the years are clearly voluminous and require a wide range of procedural, consultative, and analytical actions on the part of the agencies. It is also clear that federal agencies sometimes take years to develop final rules. For example, last year, the National Advisory Committee on Occupational Safety and Health noted that it takes OSHA an average of 10 years to develop and promulgate a health or safety standard.<sup>1</sup> Although we have reported on many federal rulemaking requirements, we have not examined the extent to which those requirements are responsible for the long time frames that are sometimes required to develop and publish final rules. Our reviews do, however, demonstrate that the requirements are frequently not as effective as expected or as they could be. In some cases that lack of effectiveness can be traced to how the requirements have been implemented by the agencies. In other cases, though, the requirements themselves seem to be the problem. Specifically,

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<sup>1</sup>National Advisory Committee on Occupational Safety and Health, *Report and Recommendations Related to OSHA's Standards Development Process*, June 6, 2000.

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the requirements were written in such a way that they do not apply to many rules, do not require substantial additional effort by the regulatory agencies, or give the agencies broad discretion in how key terms could be defined and, therefore, whether certain rulemaking actions are required.

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## Statutory Rulemaking Requirements

Some of the statutory rulemaking requirements that Congress has enacted over the years apply to all agencies, but some of the requirements are applicable only to certain agencies. Some of these requirements have been in place for more than 50 years, but most have been implemented within the past 20 years or so.

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### Administrative Procedure Act

The most long-standing and broadly applicable federal rulemaking requirements are in the Administrative Procedure Act (APA) of 1946. The APA provides for both formal and informal rulemaking. Formal rulemaking is used in ratemaking proceedings and in certain other cases when rules are required by statute to be made “on the record” after an opportunity for a trial-type agency hearing. Informal or “notice and comment” rulemaking is used much more frequently, and is the focus of my comments here today.

In informal rulemaking, the APA generally requires that agencies publish a notice of proposed rulemaking (NPRM) in the *Federal Register*.<sup>2</sup> The notice must contain (1) a statement of the time, place, and nature of public rulemaking proceedings; (2) reference to the legal authority under which the rule is proposed; and (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved. “Interested persons” must then be given an opportunity to comment on the proposed rule. The APA does not specify the length of this comment period, but agencies commonly allow at least 30 days. After considering the public comments, the agency may then publish the final rule in the *Federal Register*. According to the APA, a final rule cannot become effective until at least 30 days after its publication unless (1) the rule grants or recognizes an exemption or relieves a restriction, (2) the rule is an interpretative rule or statement of policy, or (3) the agency determines that the rule should

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<sup>2</sup>Some agencies begin the rulemaking process by publishing an “advance notice of proposed rulemaking” or ANPR in which the agency notifies the public that it is considering an area for rulemaking and often requests comments on the appropriate scope or topics of the rule. The APA does not require the use of ANPRs, but some other statutes require it for particular types of rules.

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take effect sooner for good cause and publishes that determination with the rule.

The APA also states that the notice and comment procedures generally do not apply when an agency finds, for “good cause,” that those procedures are “impracticable, unnecessary, or contrary to the public interest.”<sup>3</sup> When agencies use the good cause exception, the act requires that they explicitly say so and provide a rationale for the exception’s use when the rule is published in the *Federal Register*. Two procedures for noncontroversial and expedited rulemaking actions have been developed that are essentially applications of the good cause exception. “Direct final” rulemaking involves agency publication of a rule in the *Federal Register* with a statement that the rule will be effective on a particular date unless an adverse comment is received within a specified period of time (e.g., 30 days). If an adverse comment is filed, the direct final rule is withdrawn and the agency may publish the rule as a proposed rule. In “interim final” rulemaking, the agency issues a final rule without an NPRM that is generally effective immediately, but with a post-promulgation opportunity for the public to comment. If the public comments persuade the agency that changes are needed in the interim final rule, the agency may revise the rule by publishing a final rule reflecting those changes.

In August 1998, we reported that about half of the 4,658 final regulatory actions published in the *Federal Register* during 1997 were issued without NPRMs.<sup>4</sup> Although most of the final actions without NPRMs appeared to involve administrative or technical issues with limited applicability, some were significant actions, and 11 were “economically significant” (e.g., had at least a \$100 million impact on the economy). Some of the explanations that the agencies offered in the preambles to their rules for using the good cause exception were not clear. For example, in several cases, the preambles said that an NPRM was “impracticable” because of statutory or other deadlines that had already passed by the time the rules were issued. In other cases, the agencies asserted in the preambles that notice and comment would delay rules that were, in some general way, in the “public

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<sup>3</sup>The APA also provides exceptions to the NPRM requirement for certain categories of regulatory action (e.g., rules dealing with military or foreign affairs). It also states that the notice and comment procedures do not apply to interpretive rules; general statements of policy; or rules of agency organization, procedure, or practice.

<sup>4</sup>*Federal Rulemaking: Agencies Often Published Final Actions Without Proposed Rules* (GAO/GGD-98-126, Aug. 31, 1998).

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interest.” For example, in one such case, the agency said it was using the good cause exception because the rule would “facilitate tourist and business travel to and from Slovenia,” and therefore delaying the rule to allow for public comments “would be contrary to the public interest.” In another case, the agency said that soliciting public comments on the rule was “contrary to the public interest” because the rule authorized a “new and creative method of financing the development of public housing.”

The APA recognizes that NPRMS are not always practical, necessary, or in the public interest. However, when agencies publish final rules without NPRMs, the public’s ability to participate in the rulemaking process is limited. Also, several of the regulatory reform requirements that Congress has enacted during the past 20 years use as their trigger the publication of an NPRM. Therefore, it is important that agencies clearly explain why notice and comment procedures are not followed. We recommended in our report that OMB notify executive departments and agencies that (1) their explanations in the preambles to their rules should clearly explain why notice and comment was impracticable, unnecessary, or not in the public interest, and (2) OMB would, as part of its review of significant final rules, focus on those explanations.

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## Paperwork Reduction Act

Another statutory requirement that is applicable to both independent and non-independent regulatory agencies is the Paperwork Reduction Act (PRA), which was originally enacted in 1980 but was amended and recodified in 1995. The original PRA established the Office of Information and Regulatory Affairs (OIRA) within OMB to provide central agency leadership and oversight of governmentwide efforts to reduce unnecessary paperwork and improve the management of information resources. Under the act, agencies must receive OIRA approval for each information collection request before it is implemented. The act generally defines a “collection of information” as the obtaining or disclosure of facts or opinions by or for an agency by 10 or more non-federal persons. Many information collections, recordkeeping requirements, and third-party disclosures are contained in or are authorized by regulations as monitoring or enforcement tools, while others appear in separate written questionnaires.

Under the PRA, agencies must generally provide the public with an opportunity to comment on a proposed information collection by publishing a 60-day notice in the *Federal Register*. For each proposed collection of information submitted to OIRA, the responsible agency must certify and provide a record of support that the collection, among other

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things, is necessary for the proper performance of the functions of the agency, is not unnecessarily duplicative of other information, reduces burden on the public to the extent practicable and appropriate, and is written in plain and unambiguous terminology. The agency must also publish a notice in the *Federal Register* stating that the agency has submitted the proposed collection to OIRA and setting forth, among other things, (1) a description of the need and proposed use of the information, (2) a description of the likely respondents and their proposed frequency of response, and (3) an estimate of the resultant burden.

For any proposed information collection that is not contained in a proposed rule, OIRA must complete its review of an agency information collection request within 60 days of the date that the proposed collection is submitted. OIRA approvals can be for up to 3 years, but can be renewed by resubmitting their information collection requests to OIRA. Agency information collections that have not been approved by OIRA or for which approvals have expired are considered violations of the PRA, and those individuals and organizations subject to these collections' requirements cannot be penalized for failing to provide the information requested.

The PRA also requires OIRA to set governmentwide and agency-specific burden reduction goals. The act envisioned a 35-percent reduction in governmentwide paperwork burden by the end of fiscal year 2000. However, earlier this year we testified that governmentwide paperwork burden has gone up, not down, since 1995.<sup>5</sup> Federal agencies often indicate that they cannot reduce their paperwork burden because of existing and new statutory requirements that they collect more information. Nevertheless, some agencies do appear to be making progress. For example, the Department of Labor's paperwork estimate dropped from more than 266 million burden hours at the end of fiscal year 1995 to about 182 million burden hours at the end of fiscal year 2000—a 32 percent decrease.

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## Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), enacted in 1980 in response to concerns about the effect that federal regulations can have on small entities, is another example of a broadly-based rulemaking requirement. Under the RFA, independent and non-independent regulatory agencies

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<sup>5</sup>*Paperwork Reduction Act: Burden Estimates Continue to Increase* ([GAO-01-648T](#), Apr. 24, 2001).

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must prepare an initial regulatory flexibility analysis at the time proposed rules are issued unless the head of the issuing agency determines that the proposed rule would not have a “significant economic impact upon a substantial number of small entities.”<sup>6</sup> The regulatory flexibility analysis must include a description of, among other things, (1) the reasons why the regulatory action is being considered; (2) the small entities to which the proposed rule will apply and, where feasible, an estimate of their number; (3) the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, and (4) any significant alternatives to the proposed rule that accomplish the statutory objectives and minimize any significant economic impact on small entities. The RFA also requires agencies to ensure that small entities have an opportunity to participate in the rulemaking process, and requires the Chief Counsel of the Small Business Administration’s (SBA) Office of Advocacy to monitor agencies’ compliance with the Act. Section 610 of the RFA requires agencies to review those rules that have or will have a significant impact within 10 years of their promulgation to determine whether they should be continued without change or should be amended or rescinded to minimize their impact on small entities.

We have reported on the implementation of the RFA on several occasions in the past, and a recurring theme in our reports is the varying interpretation of the RFA’s requirements by federal agencies. For example, in 1991, we reported that each of the four federal agencies that we reviewed had a different interpretation of key RFA provisions.<sup>7</sup> The report pointed out that the RFA provided neither a mechanism to enforce compliance with the act nor guidance on implementing it. We recommended that Congress consider amending the RFA to require that SBA develop criteria for whether and how federal agencies should conduct RFA analyses.

In 1994 we examined the 12 SBA annual reports on agencies’ RFA compliance that had been issued since 1980.<sup>8</sup> The reports indicated that

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<sup>6</sup>The agency must prepare a final regulatory flexibility analysis at the time the final rule is issued unless the agency head makes a determination that the rule will not have a significant economic impact on a substantial number of small entities.

<sup>7</sup>*Regulatory Flexibility Act: Inherent Weaknesses May Limit Its Usefulness for Small Governments* ([GAO/HRD-91-16](#), Jan. 11, 1991).

<sup>8</sup>*Regulatory Flexibility Act: Status of Agencies’ Compliance* ([GAO/GGD-94-105](#), Apr. 27, 1994).

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agencies' compliance with the RFA varied widely from one agency to another, and that some agencies' compliance varied over time. We noted that the RFA does not expressly authorize SBA to interpret key provisions of the statute, and does not require SBA to develop criteria for agencies to follow in reviewing their rules. As a result, different rulemaking agencies were interpreting the statute differently. We said that if Congress wanted to strengthen the implementation of the RFA it should consider amending the act to provide SBA with clearer authority and responsibility to interpret the RFA's provisions and require SBA to develop criteria on whether and how agencies should conduct RFA analyses.

We essentially repeated this recommendation in our 1999 report on the review requirements in section 610 of the RFA that the agencies we reviewed differed in their interpretation of those review requirements.<sup>9</sup> We said that if Congress was concerned about these varying interpretations it might wish to consider clarifying those provisions. Last year we reported on the implementation of the RFA at EPA and concluded that, although the agency had established a high threshold for what constitutes a significant economic impact, the agency's determinations were within the broad discretion that the statute allowed.<sup>10</sup> We again said that Congress could take action to clarify the act's requirements and help prevent concerns about how agencies are implementing the act. Earlier this year we testified on the need for congressional action in this area, noting that the promise of the RFA may never be realized until Congress or some other entity defines what a "significant economic impact" and a "substantial number of small entities mean in a rulemaking setting.<sup>11</sup> To date, Congress has not acted on our recommendations.

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## Small Business Regulatory Enforcement Fairness Act

The RFA was amended in 1996 by the Small Business Regulatory Enforcement Fairness Act (SBREFA) to, among other things, make certain agency actions under the act judicially reviewable. For example, a small entity that is adversely affected or aggrieved by an agency's determination that its final rule would not have a significant impact on small entities

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<sup>9</sup>*Regulatory Flexibility Act: Agencies' Interpretations of Review Requirements Vary* ([GAO/GGD-99-55](#), Apr. 2, 1999).

<sup>10</sup>*Regulatory Flexibility Act: Implementation in EPA Program Offices and Proposed Lead Rule* ([GAO/GGD-00-193](#), Sept. 20, 2000).

<sup>11</sup>*Regulatory Flexibility Act: Key Terms Still Need to Be Clarified* ([GAO-01-669T](#), Apr. 24, 2001).

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could generally seek judicial review of that determination within 1 year of the date of the final agency action. In granting relief, a court may remand the rule to the agency or defer enforcement against small entities. SBA's Office of Advocacy noted in a report marking the 20th anniversary of the RFA that the addition of judicial review has been an incentive for agencies to comply with the act's requirements, and that small entities are not hesitant to initiate court challenges in appropriate cases.<sup>12</sup>

Another provision of SBREFA requires OSHA and the Environmental Protection Agency (EPA) to convene advocacy review panels before publishing an initial regulatory flexibility analysis. Specifically, the agency issuing the regulation (OSHA or EPA) must notify the SBA Chief Counsel for Advocacy and provide information on the draft rule's potential impacts on small entities and the type of small entities that might be affected. The Chief Counsel then must identify representatives of affected small entities within 15 days of the notification. SBREFA requires the panel to consist of full-time federal employees from the rulemaking agency, OIRA, and SBA's Chief Counsel for Advocacy. During the advocacy review panel process, the panel must collect the advice and recommendations of representatives of affected small entities about the potential impact of the draft rule. SBREFA also states that the panel must report on the comments received and on the panel's recommendations no later than 60 days after the panel is convened, and the panel's report must be made public as part of the rulemaking record.

In 1998 we reported on how the first five advocacy review panels were implemented, including OSHA's panel on occupational exposure to tuberculosis.<sup>13</sup> Agency officials and small entity representatives generally agreed that the panel process was worthwhile, providing valuable insights and opportunities for participation in the rulemaking process. However, some of the small entity representatives believed that the panels should be held earlier in the process, that the materials provided to them and the amount of time provided for their review could be improved, and that the agencies should improve the means by which they obtain comments. We noted that the trigger for the panel process is an agency's initial determination that a rule may have a significant economic impact on a

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<sup>12</sup>U.S. Small Business Administration, *20 Years of the Regulatory Flexibility Act: Rulemaking in a Dynamic Economy* (Washington, DC, 2000).

<sup>13</sup>*Regulatory Reform: Implementation of the Small Business Advocacy Review Panel Requirements* ([GAO/GGD-98-36](#), Mar. 18, 1998).

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substantial number of small entities, and again recommended that Congress give some entity clear authority and responsibility to interpret the RFA's provisions.

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### Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (UMRA) is an example of a statutory requirement that appears to have had little substantive effect on agency rulemaking. For example, title II of UMRA generally requires covered federal agencies to prepare written statements containing specific information for any rule for which a proposed rule was published that includes a federal mandate that may result in the expenditure of \$100 million or more in any 1 year by state, local, and tribal governments, in the aggregate, or by the private sector. The statute defined a "federal mandate" as not including conditions imposed as part of a voluntary federal program or as a condition of federal assistance.

We examined the implementation of title II of UMRA during its first 2 years and concluded that it appeared to have only limited direct impact on agencies' rulemaking actions.<sup>14</sup> Most of the economically significant rules promulgated during that period were not subject to the act's requirements for a variety of reasons (e.g., no proposed rule, or the mandates were a condition of federal assistance or part of a voluntary program). There were only two rules without an UMRA written statement that we believed should have had one (EPA's proposed national ambient air quality standards for ozone and particulate matter), but even in those rules we believed that the agency had satisfied the substantive UMRA written statement requirements. Also, title II contains exemptions that allowed agencies not to take certain actions if they determined that they were duplicative or not "reasonably feasible." The title also required agencies to take certain actions that they already were required to take or had completed or that were already under way.

### National Environmental Policy Act

Another crosscutting rulemaking requirement of note is the National Environmental Policy Act of 1969 (NEPA). NEPA requires federal agencies to include in every recommendation or report related to "major Federal actions significantly affecting the quality of the human environment" a detailed statement on the environmental impact of the proposed action.

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<sup>14</sup>*Unfunded Mandates: Reform Act Has Had Little Effect on Agencies' Rulemaking Actions* (GAO/GGD-98-30, Feb. 4, 1998).

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According to the act and its implementing regulations developed by the Council on Environmental Quality, the statement must delineate the direct, indirect, and cumulative effects of the proposed action.<sup>15</sup> Agencies are also required to include in the statement (1) any adverse environmental effects that cannot be avoided should the proposal be implemented, (2) alternatives to the proposed action, (3) the relationship between local short-term uses of the environment and the maintenance and enhancement of long-term productivity, and (4) any irreversible and irretrievable commitments of resources that would be involved if the proposed action should be implemented. Before developing any such environmental impact statement, NEPA requires the responsible federal official to consult with and obtain comments of any federal agency that has jurisdiction by law or special expertise with respect to any environmental impact involved. Agencies must make copies of the statement and the comments and views of appropriate federal, state, and local agencies available to the president, the Council on Environmental Quality, and to the public. The adequacy of an agency's environmental impact statement is subject to judicial review.

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## Other Statutory Requirements

The crosscutting statutory requirements that I have just listed are by no means the only statutory requirements that guide agency rulemaking. Regulations generally start with an act of Congress and are the means by which statutes are implemented and specific requirements are established. The statutory basis for a regulation can vary in terms of its specificity, from very broad grants of authority that state only the general intent of the legislation to very specific requirements delineating exactly what regulatory agencies should do and how they should do it. In 1999, we issued a report that examined this issue of regulatory discretion, and we reported that in many of the cases that we examined the statutes gave the agencies little or no discretion in establishing regulatory requirements that businesses viewed as burdensome.<sup>16</sup> For example, we concluded that the Occupational Safety and Health Act gave OSHA no discretion in whether to hold companies (rather than individual employees) responsible for health and safety violations. Also, as other witnesses today will likely describe in detail, OSHA also follows numerous procedural and consultative steps before issuing a rule that may or may not be statutorily

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<sup>15</sup>The NEPA regulations are codified at 40 CFR Parts 1500-1508.

<sup>16</sup>*Regulatory Burden: Some Agencies' Claims Regarding Lack of Rulemaking Discretion Have Merit* ([GAO/GGD-99-20](#), Jan. 8, 1999).

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driven. For example, interested parties who comment on proposed OSHA rules may request a public hearing when none has been announced in the notice. When such a hearing is requested, OSHA says it will schedule one, and will publish in advance the time and place for it in the *Federal Register*. Therefore, federal agencies must be aware of the statutory requirements underlying their regulations, and must craft rules that are consistent with those requirements.

Similarly, agency rulemaking is often significantly influenced by court decisions interpreting statutory requirements, and OSHA rulemaking is a good case in point. For example, in its 1980 “Benzene” decision, the Supreme Court ruled that, before promulgating new health standards, OSHA must demonstrate that the particular chemical to be regulated poses a “significant risk” under workplace conditions permitted by current regulations.<sup>17</sup> The court also said that OSHA must demonstrate that the new limit OSHA proposes will substantially reduce that risk. This decision effectively requires OSHA to evaluate the risks associated with exposure to a chemical and to determine that these risks are “significant” before issuing a standard. Other court decisions have required OSHA rulemaking to demonstrate the technical and economic feasibility of its requirements.<sup>18</sup>

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## Executive Orders/Presidential Directives

During the past 20 years, each president has issued executive orders and/or presidential directives designed to guide the federal rulemaking process, often with the goal of reducing regulatory burden. Although independent regulatory agencies are generally not covered by these requirements, they are often encouraged to follow them.

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## Regulatory Planning and Review

One of the most important of the current set of executive orders governing the rulemaking process is Executive Order 12866, “Regulatory Planning and Review,” which was issued by President Clinton in September 1993. Under the order, non-independent regulatory agencies are required to submit their “significant” rules to OIRA before publishing them in the *Federal Register* at both the proposed and final rulemaking stages. OIRA must generally notify the agency of the results of its review of a proposed

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<sup>17</sup>*Industrial Union Department v. American Petroleum Institute*, 448 U.S. 607 (1980).

<sup>18</sup>See, for example, *American Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490 (1981) and *United Steelworkers v. Marshall*, 647 F.2d 1189 (D.C. Cir. 1980), cert. denied, 453 U.S. 913 (1981).

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or final rule within 90 calendar days after the date the rule and related analyses are submitted.<sup>19</sup> The agencies are required to submit the text of the draft regulatory action and an assessment of the potential costs and benefits of the action to OIRA. They are required to submit a detailed economic analysis for any regulatory actions that are “economically significant” (e.g., have annual effects on the economy of \$100 million or more).<sup>20</sup> According to the executive order, the analyses should include an assessment of the costs and benefits anticipated from the action as well as the costs and benefits of “potentially effective and reasonably feasible alternatives to the planned regulation.” The order also states that, in choosing among alternatives, an agency should select those approaches that maximize net benefits and “base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.”

In January 1996, OMB issued “best practices” guidance on preparing cost-benefit analyses under the executive order. The guidance gives agencies substantial flexibility regarding how the analyses should be prepared, but also indicates that the analyses should contain certain basic elements and should be “transparent”—disclosing how the study was conducted, what assumptions were used, and the implications of plausible alternative assumptions.

At the request of Members of Congress, we have examined agencies’ economic analyses both in our reviews of selected federal rules issued by multiple agencies and in the context of particular regulatory actions. In one of our reviews, we reported that some of the 20 economic analyses from five agencies that we reviewed did not incorporate all of the best practices set forth in OMB’s guidance.<sup>21</sup> Five of the analyses did not discuss alternatives to the proposed regulatory action, and, in many cases, it was not clear why the agencies used certain assumptions. Also, five of the analyses did not discuss uncertainty associated with the agencies’ estimates of benefits and/or costs, and did not document the agencies’ reasons for not doing so. We recommended that OMB’s best practices

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<sup>19</sup>OIRA must complete its review within 45 days if it has previously reviewed the rule and the facts and circumstances are substantially unchanged.

<sup>20</sup>Similar economic analysis requirements had previously been in place under Executive Order 12291, issued by President Reagan in 1981.

<sup>21</sup>*Regulatory Reform: Agencies Could Improve Development, Documentation, and Clarity of Regulatory Economic Analyses* ([GAO/RCED-98-142](#), May 26, 1998).

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guidance be amended to provide that economic analyses should (1) address all of the best practices or state the agency's reason for not doing so, (2) contain an executive summary, and (3) undergo an appropriate level of internal or external peer review by independent experts. To date, OMB has not acted on our recommendations.

Executive Order 12866 also includes several other notable requirements. For example, section 5 of the order requires agencies to periodically review their existing significant regulations to determine whether they should be modified or eliminated. In March 1995, President Clinton reemphasized this requirement by directing each agency to conduct a page-by-page review of all existing regulations. In June 1995, the President announced that 16,000 pages had been eliminated from the Code of Federal Regulations. We reported on this review effort in October 1997, noting that the page elimination totals that four agencies reported did not take into account pages that had been added while the eliminations took place.<sup>22</sup> We also said that about 50 percent of the actions taken appeared to have no effect on the burden felt by regulated entities, would have little effect, or could increase regulatory burden.

Another part of the executive order requires agencies to prepare an agenda of all regulations under development or review and a plan describing in greater detail the most important regulatory actions that the agency expects to issue in proposed or final form in the next fiscal year or thereafter. The order also requires agencies to identify for the public in a complete, clear, and simple manner the substantive changes that are made to rules while under review at OIRA and, separately, the changes made at the suggestion or recommendation of OIRA. In January 1998 we reported on the implementation of this requirement, and concluded that the four agencies we reviewed had complete documentation available to the public of these changes for only about one-quarter of the 122 regulatory actions that we reviewed.<sup>23</sup> OSHA had complete documentation available for one of its three regulatory actions, but the information was contained in files separate from the public rulemaking docket to ensure that it did not become part of the official rulemaking record and, therefore, subject to litigation.

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<sup>22</sup>*Regulatory Reform: Agencies' Efforts to Eliminate and Revise Rules Yield Mixed Results* ([GAO/GGD-98-3](#), Oct. 2, 1997).

<sup>23</sup>*Regulatory Reform: Changes Made to Agencies' Rules Are Not Always Clearly Documented* ([GAO/GGD-98-31](#), Jan. 8, 1998).

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## Federalism Executive Order

Executive Order 12612 on “Federalism,” issued by President Reagan in 1987, was similar to the RFA in that it gave federal agencies broad discretion to determine the applicability of its requirements. The executive order required the head of each federal agency to designate an official to be responsible for determining which proposed policies (including regulations) had “sufficient federalism implications” to warrant preparation of a federalism assessment. If the designated official determined that such an assessment was required, it had to accompany any proposed or final rule submitted to OMB for review.

We examined the preambles of more than 11,000 final rules that federal agencies issued between April 1996 and December 1998 to determine how often they mentioned the executive order and how often the agencies indicated that they had prepared a federalism assessment.<sup>24</sup> Our work indicated that Executive Order 12612 had relatively little visible effect on federal agencies’ rulemaking actions during this time frame. The preambles to only 5 of the more than 11,000 rules indicated that the agencies had conducted a federalism assessment.

Most of these rules were technical or administrative in nature, but 117 were economically significant rules. However, the agencies prepared a federalism assessment for only one of these economically significant rules. The lack of assessments for these rules is particularly surprising given that the agencies had previously indicated that 37 of the rules would affect state and local governments, and said that 21 of them would preempt state and local laws in the event of a conflict.

Federal agencies had broad discretion under Executive Order 12612 to determine whether a proposed policy has “sufficient” federalism implications to warrant the preparation of a federalism assessment. Some agencies have clearly used that discretion to establish an extremely high threshold. For example, in order for an EPA rule to require a federalism assessment, the agency’s guidance said that the rule must, among other things, have an “institutional” effect on the states (not just a financial effect), and affect all or most of the states in a direct, causal manner. Under these standards, an EPA regulation that has a substantial financial

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<sup>24</sup>*Federalism: Previous Initiatives Have Had Little Effect on Agency Rulemaking* (GAO/T-GGD-99-31, June 30, 1999).

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effect on all states, but does not affect the “institutional” role of the states, would not require a federalism assessment.

Executive Order 12612 was revoked by President Clinton’s Executive Order 13132 on “Federalism,” which was issued August 4, 1999, and took effect on November 2, 1999. Like the old executive order, the new order provides agencies with substantial flexibility to determine which of their actions have “federalism implications” and, therefore, when they should prepare a “federalism summary impact statement.”

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Other Executive Orders and Directives	Non-independent regulatory agencies are also covered by an array of other executive orders and presidential directives or memoranda. These executive requirements include:
	<ul style="list-style-type: none"><li>• Executive Order 13175, which requires consultation and coordination with Indian tribal governments. Agencies submitting final rules to OIRA under Executive Order 12866 must certify that this order’s requirements were “met in a meaningful and timely manner.”</li><li>• Executive Order 12988 on civil justice reform, which generally requires agencies to review existing and new regulations to ensure that they comply with specific requirements (e.g., “eliminate drafting errors and ambiguity” and “provide a clear legal standard for affected conduct”) to improve regulatory drafting in order to minimize litigation.</li><li>• Executive Order 12630 on constitutionally protected property rights, which says each agency “shall be guided by” certain principles when formulating or implementing policies that have “takings” implications. For example, the order says that private property should be taken only for “real and substantial threats,” and “be no greater than is necessary.”</li><li>• Executive Order 12898 on environmental justice, which says (among other things) that each agency must develop a strategy that identifies and addresses disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low income populations. It also says that agencies should identify rules that should be revised to meet the objectives of the order.</li><li>• Executive Order 13045 on protection of children from environmental health risks and safety risks. The order says that for any substantive rulemaking action that is likely to result in an economically significant rule that concerns an environmental health risk or safety risk that may disproportionately affect children, the agency must provide OIRA (1) an evaluation of the environmental or safety effects on children and (2) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives.</li></ul>

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- Executive Order 12889 on the North American Free Trade Agreement, which generally requires agencies subject to the APA to provide at least a 75-day comment period for any “proposed Federal technical regulation or any Federal sanitary or phytosanitary measure of general application.”
  - Various presidential memoranda or directives. For example, a March 4, 1995, presidential memorandum directed agencies to, among other things, focus their regulatory programs on results not process and expand their use of negotiated rulemaking. A June 1, 1998, presidential directive required agencies to use plain language in proposed and final rulemaking documents.

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## Congressional Review Act

One statutory requirement that I did not mention previously but that can clearly affect agency rulemaking is the Congressional Review Act (CRA), which was included as part of SBREFA in 1996. Under the CRA, before a final rule can become effective it must be filed with Congress and GAO. If OIRA considers the rule to be “major” (e.g., has a \$100 million impact on the economy), the agency must delay its effective date by 60 days after the date of publication in the *Federal Register* or submission to Congress and GAO, whichever is later. Within 60 legislative or session days, a Member of Congress can introduce a resolution of disapproval that, if adopted by both Houses and signed by the president, can nullify the agency’s rule.

GAO’s major role under CRA is to provide Congress with a report on each major rule concerning GAO’s assessment of the issuing agency’s compliance with the procedural steps required by the various acts and executive orders governing the rulemaking process. Our report must be sent to the congressional committees of jurisdiction within 15 calendar days, so our review is limited to a description of the issuing agency’s rulemaking actions.<sup>25</sup> We also collect basic information about the nonmajor rules that agencies issue. Information about both major and nonmajor rules is available on our web site ([www.gao.gov](http://www.gao.gov)). As of last

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<sup>25</sup>Last year, Congress gave GAO a new and more substantive regulatory oversight responsibility through passage of the Truth in Regulating Act of 2000 (TIRA). Under TIRA, the chairman or ranking member of any committee of jurisdiction can request an in-depth review of the agency’s estimate of a proposed or final economically significant rule’s costs and benefits, an analysis of the alternatives that the agency considered, and the agency’s compliance with relevant procedural and analytical requirements. Federal agencies are required to “promptly cooperate” with GAO in carrying out the act. However, TIRA established a 3-year pilot project that became effective upon the specific annual appropriation of \$5.2 million (or the prorated portion thereof). To date, Congress has not provided that appropriation.

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week, GAO had received more than 22,000 rules since the CRA took effect in March 1996, of which nearly 350 have been considered major under the act. OSHA had issued only 28 rules since March 1996, of which 6 were major rules.

Although the CRA has only a modest direct impact on regulatory agencies' rulemaking processes, Congress' use of the statute to disapprove rules may have a decided indirect impact on how other rulemaking requirements are implemented. To date, Congress has used its disapproval power only one time—the disapproval of OSHA's ergonomics standard earlier this year.

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Mr. Chairman, this completes my prepared statement. I would be pleased to answer any questions.